

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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TAKEDA CHEMICAL INDUSTRIES, LTD. and :
TAKEDA PHARMACEUTICALS, NORTH AMERICA, :
INC., : 03 Civ. 8253 (DLC)
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Plaintiffs, :
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-v- :
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MYLAN LABORATORIES, INC. and UDL :
LABORATORIES, INC., :
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Defendants. :
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MEMORANDUM OPINION
AND ORDER

DENISE COTE, District Judge:

On September 8, 2003, defendant Mylan Laboratories, Inc. ("Mylan") sent a Notice of Paragraph IV certification to plaintiff Takeda Chemical Industries, Ltd. ("Takeda"), in which it informed Takeda that it had submitted an ANDA regarding the sale of pioglitazone before the expiration of certain patents ("September 8 Notice"). In that notice, Mylan described its belief that U.S. Patent No. 4,687,777 (the "'777 Patent") was invalid on the basis of obviousness due to Compound 16 of U.S. Patent No. 4,287,200 (the "'200 Patent"). Mylan asserted that Compound 16 of the '200 Patent is identical to a Compound 14 identified in a prior publication of Dr. Sohda.

On March 17, 2005, Takeda served contention interrogatories on Mylan, in which Takeda requested that Mylan detail its contentions as to the invalidity of the '777 Patent. Mylan's response of April 25, 2005 did not touch upon the obviousness of

the '777 Patent. Instead, Mylan contended that the '777 Patent was unenforceable on the basis that Takeda had breached its duty of good faith and candor in applying to the PTO for the '777 Patent. Additionally, on June 2 and 3, 2005, Takeda deposed a representative of Mylan pursuant to Rule 30(b)(6), Fed. R. Civ. P. At that deposition, Takeda inquired as to the bases for Mylan's contentions that the '777 Patent is invalid, unenforceable, or not infringed, other than those disclosed in the September 8 Notice. At several points, Mylan's counsel objected to this line of questioning, citing the attorney-client and work product privileges. After the close of fact discovery, on June 6, 2005, Mylan served supplemental responses to Takeda's interrogatories, in which it expresses that the '777 Patent is invalid on the basis of obviousness due to a previously unmentioned compound, Compound 57, as described in the Sohda publication.

On June 14, Takeda wrote a letter seeking an order precluding Mylan from introducing at trial any evidence as to invalidity of the '777 Patent except based on obviousness as set forth in the September 8 Notice. Pursuant to a June 15 Order, the parties submitted additional correspondence concerning this issue. In its submission, Mylan emphasizes Smithkline Beecham Corp. v. Apotex Corp., No. 98 C 3952, 2000 WL 116082 (N.D. Ill. Jan. 24, 2000), which it cites for the proposition that there is


"no authority for limiting [a defendant] to the theories set forth i[n] their notice letter."

Mylan misunderstands the law. Although as a general matter an ANDA applicant may be able to assert theories other than those outlined in a notification letter, "when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs the trial. . . . [A] specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 551 (Fed. Cir. 1998). During the period of fact discovery, Mylan never articulated any basis for the invalidity of the '777 Patent on the ground of obviousness other than Compound 14 of the Sohda publication. Therefore, it is hereby

ORDERED that Mylan may not offer at trial any evidence as to invalidity of the '777 Patent except based on a theory of obviousness set forth in the September 8 Notice.

SO ORDERED:

Dated: New York, New York
June 15, 2005



DENISE COTE
United States District Judge